4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0079]

Hikma Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of 29 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 29 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 006134	Dolophine (methadone hydrochloride (HCl)) Tablets, 5 milligrams (mg), and 10 mg Dolophine (methadone HCl) Syrup, 10 mg/30 milliliter (mL)	Hikma Pharmaceuticals USA, Inc., 1809 Wilson Rd., Columbus, OH 43228
NDA 006882	Phisohex (hexachlorophene) Emulsion, 3%	Sanofi-aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807
NDA 009818	Kemadrin (procyclidine HCl) Tablets, 2 mg, and 5 mg	Monarch Pharmaceuticals, LLC, c/o Pfizer, Inc., 235 East 42nd St., New York, NY 10017
NDA 012301	Librium (chlordiazepoxide HCl), Injection, 100 mg/ampule	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
NDA 013416	Norgesic (orphenadrine citrate, aspirin, and caffeine) Tablets, 25 mg/385 mg/30 mg Norgesic Forte (orphenadrine citrate, aspirin, and caffeine) Tablets, 50 mg/770 mg/60 mg	Bausch Health US, LLC
NDA 014228	Spandin (aspirin and sodium salicylate) Time-released Tablets, 7.5 grains/2.5 grains	Abbott Healthcare Pvt. Ltd., c/o G&L Scientific, Independence Blvd., 4th Floor, Warren, NJ 07059
NDA 016194	Talwin (pentazocine lactate) Injection, equivalent to (EQ) 30 mg base/mL	Hospira Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
NDA 016418	Inderal (propranolol HCl) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, 80 mg, and 90 mg	Wyeth Pharmaceuticals LLC, 235 E. 42nd St., New York, NY 10017
NDA 016704	Resectisol (mannitol) Irrigation Solution, 5 grams (g)/100 mL	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109
NDA 016762	Inderal (propranolol HCl) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, and 80 mg	Wyeth Pharmaceuticals LLC
NDA 016954	Micronor (norethindrone) Tablets, 0.35 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560
NDA 017013	Sodium Chloride Injection, 20 g/ 100 mL	Abbott Healthcare Pvt. Ltd., c/o G&L Scientific
NDA 017683	Inderal (propranolol HCL) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, and 80 mg	Wyeth Pharmaceuticals LLC

NDA 018423	Hibiclens (chlorhexidine gluconate) Sponge, 4%	Mölnlycke Health Care, 5445 Triangle Pkwy., Suite 400, Peachtree Corners, GA 30092
NDA 018703	Zantac (ranitidine HCl) Tablets, EQ 150 mg base, and EQ 300 mg base	GlaxoSmithKline Intellectual Property Ltd. England, c/o GlaxoSmithKline, 5 Crescent Dr., Philadelphia, PA 19112
NDA 019387	Profenal (suprofen) Ophthalmic Solution, 1%	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134-2099
NDA 019530	Ucephan (sodium benzoate and sodium phenylacetate) Solution, 100 mg/mL; 100 mg/mL	B. Braun Medical Inc.
NDA 019675	Zantac (ranitidine HCl) Syrup, EQ 15 mg base/mL	GlaxoSmithKline Intellectual Property Ltd. England, c/o GlaxoSmithKline
NDA 019814	Betagan (levobunolol HCl) Ophthalmic Solution, 0.25%	Allergan, Inc.
NDA 019927	Nizoral (ketoconazole) Shampoo, 2%	Janssen Pharmaceuticals, Inc.
NDA 020037	Voltaren (diclofenac sodium) Ophthalmic Solution, 0.1%	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936-1080
NDA 021169	Razadyne (galantamine hydrobromide) Tablets, EQ 4 mg base, EQ 8 mg base, and EQ 12 mg base	Janssen Research & Development, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560
NDA 021204	Starlix (nateglinide) Tablets, 60 mg, and 120 mg	Novartis Pharmaceuticals Corp.
NDA 021406	Fortical (calcitonin-salmon recombinant) Nasal Spray, 200 International Units/Spray	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369
NDA 021860	Sarafem (fluoxetine HCl) Tablets, EQ 10 mg base, EQ 15 mg base, and EQ 20 mg base	Allergan Pharmaceuticals International Ltd., c/o Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940
NDA 202833	Picato (ingenol mebutate) Gel, 0.015%, and 0.05%	LEO Laboratories Ltd., c/o LEO Pharma Inc., 7 Giralda Farms, Madison, NJ 07940
NDA 202880	Zohydro ER (hydrocodone bitartrate) Extended-release Capsules, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg	Recro Gainesville LLC, 1300 Gould Dr., Gainesville, GA 30504
NDA 204683	Khedezla (desvenlafaxine) Extended-Release Tablets, 50 mg, and 100 mg	Osmotica Pharmaceutical US LLC, 400 Crossing Blvd., Bridgewater, NJ 08807

NDA 207916	Cetylev (acetylcysteine) Effervescent Tablets, 500 mg, and 2.5 g	Arbor Pharmaceuticals, LLC, 6 Concourse Pkwy., Suite 1800, Atlanta, GA 30328

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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